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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/276,868 | 03/26/1999 | MICHAEL SIMONS | BIS-043 | 2716 |

7590 07/21/2003

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MAGNOLIA, MA 01930

[REDACTED] EXAMINER

KAM, CHIH MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1653 | 25 |

DATE MAILED: 07/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/276,868 | SIMONS ET AL. |
| | Examiner | Art Unit |
| | Chih-Min Kam | 1653 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

1. Claims 11-15 are pending.

Applicants' amendment filed on May 9, 2003 (Paper No. 23) is acknowledged, and applicant's response has been fully considered. Claims 11 and 15 have been amended, and claims 11-15 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-15 are indefinite because of the use of the term "a specific peptide". The term cited "a specific peptide" renders the claim indefinite, it is unclear what peptide is intended as to "a specific peptide". Claims 12-14 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate the terms "at least one" and "against other peptides" have been deleted, and the term "a specific peptide" has been cited in the claim, which more precisely differentiates and distinguishes between the selectively inhibited proteolytic degradation mediated by proteasomes against "a specific peptide" from proteolytic degradation mediated by proteasomes "apart from against said specific peptide" which remain unaltered (pages 10-13). The argument is unpersuasive because the claim does not identify the specific peptide, thus, it is

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not clear which proteolytic activity of the proteosome is selectively inhibited by the PR-39 oligopeptide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Blecha *et al.* (WO 96-32129).

Blecha *et al.* teach PR-39 and truncated analogs such as PR-14 and PR-19 inhibit leukocyte superoxide anion production and attract leukocytes, thus, these peptides can be used as medicaments that fight infection by attracting leukocytes to a wound site to restrict tissue damage (page 3). The truncated analog PR-14 (RRRPRPPYLPRLPRP, Fig. 1) comprises the amino acid sequence of SEQ ID NO:4 (RRRPRPPYLPRLPR, claim 13) or SEQ ID NO: 5 (RRRPRPPY, claim 14), and PR-19 (RRRPRPPYLPRLPRPRPPPFFP, Fig. 1) comprises the amino acid sequence of SEQ ID NO:3 (RRRPRPPYLPRLPRPRP, claim 12). These truncated analogs of PR-39 such as PR-14 and PR-19 would be expected to have the characteristics and properties of the claimed peptides cited in the claim (claims 11 and 15) since they have the same amino acid sequences as the claimed sequence of SEQ ID NO: 3, 4 or 5.

In response, applicants indicate that the rejection made by Examiner is based solely and exclusively upon the legal doctrine of “inherency”, and the legal doctrine of “inherency” holds that anticipation (and alternatively obviousness) may be established when a prior art reference

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either discloses exactly or suggests the identical goals of a claimed invention, and also provides both the materials and the manner of using the materials to achieve the intended goal as a consequential result; the Examiner must show the prior art reference not only offer the result, consequence, or property, it must also provide compositions of matter which have the requisite structure, characteristics, and properties as well as are pharmaceutically active and functional to achieve the intended result recited by the claimed invention; and Blecha *et al.* teach the synthesized anti-microbial peptides are analogs or truncated peptides of PR-39 peptide such as PR-14, PR-19 and PR-26 peptides, however, only PR-26 analog was found to have anti-microbial activity, the PR-14 and PR-19 analogs failed to show any anti-microbial activity, thus, Blecha *et al.* only teach the limited utility of PR-26 peptide as anti-microbial agent, the reference does not teach or suggest to those skill in the art to make and use the PR-39 oligopeptides as defined by claims 11-15 (pages 13-29 of the response). The response has been fully considered, however, the argument is not found persuasive because Blecha *et al.* teach the same truncated PR-39 peptides (e.g., PR-14 and PR-19) as the oligopeptides cited in claims 12, 13 or 14, and the peptides having the same amino acid sequences would be expected to have the same property and function, thus the function of inhibiting proteosome-mediated degradation would be expected for PR-14 and PR-19, even though the cited function is not indicated in the reference. Use “a peptide consists of SEQ ID NO: 3, 4 or 5” would avoid the rejection.

Conclusion

4. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8:00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CryK*
Patent Examiner

July 20, 2003

Christopher S. Low
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